

Food and Drug Administration, HHS

§ 203.3

Subpart C—Sales Restrictions

- 203.20 Sales restrictions.
- 203.22 Exclusions.
- 203.23 Returns.

Subpart D—Samples

- 203.30 Sample distribution by mail or common carrier.
- 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).
- 203.32 Drug sample storage and handling requirements.
- 203.33 Drug sample forms.
- 203.34 Policies and procedures; administrative systems.
- 203.35 Standing requests.
- 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.
- 203.37 Investigation and notification requirements.
- 203.38 Sample lot or control numbers; labeling of sample units.
- 203.39 Donation of drug samples to charitable institutions.

Subpart E—Wholesale Distribution

- 203.50 Requirements for wholesale distribution of prescription drugs.

Subpart F—Request and Receipt Forms, Reports, and Records

- 203.60 Request and receipt forms, reports, and records.

Subpart G—Rewards

- 203.70 Application for a reward.

AUTHORITY: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

SOURCE: 64 FR 67756, Dec. 3, 1999, unless otherwise noted.

Subpart A—General Provisions

§ 203.1 Scope.

This part sets forth procedures and requirements pertaining to the re-importation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Blood and blood

components intended for transfusion are excluded from the restrictions in and the requirements of the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

§ 203.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see part 205 of this chapter), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.

§ 203.3 Definitions.

(a) *The act* means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*).

(b) *Authorized distributor of record* means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(c) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(d) *Blood component* means that part of a single-donor unit of blood separated by physical or mechanical means.

(e) *Bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) *Charitable institution or charitable organization* means a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(g) *Common control* means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership